DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

The Honorable Joe L. Barton
Ranking Member
Committee on Energy and Commerce
House of Representatives
Washington, D. C. 20515-4306

FEB 0 1 2008

Dear Mr. Barton:

Thank you for the letter of November 14, 2007, cosigned by former Ranking Member, Ed Whitfield, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce. Your letter requests information regarding the Food and Drug Administration's (FDA or Agency) dispute resolution process, and specifically references a Warning Letter dispute and related civil money penalty case involving a medical device firm. Please be assured that FDA invests significant time and resources to carry out its public health mandate, and does not issue a Warning Letter or commence an enforcement action unless there is clear evidence of a statutory or regulatory violation.

The Agency routinely affords regulated entities with notice of potential violations of the Federal, Food, Drug, and Cosmetic Act and the opportunity to voluntarily correct such violations before initiating an enforcement action. See *FDA Regulatory Procedures Manual*, March 2004, Chapter 10, Section 10-1, "Prior Notice" available at: *http://www.fda.gov/ora/compliance_ref/rpm/pdf/ch10.pdf.* FDA generally is under no legal obligation to warn individuals or firms that they or their products are in violation of the law before taking enforcement action. The Agency issues Warning Letters based on the expectation that most individuals and firms will voluntarily comply with the law. In determining whether to issue a Warning Letter, FDA considers several factors, including the significance of the violations, the firm's history of similar violations, and whether the failure to correct the violations may lead to an enforcement action. Achieving voluntary compliance through the Warning Letter process allows the Agency to focus its limited enforcement resources on persons who do not voluntarily comply with the law and matters that have the most significant public health impact.

Most firms respond to Warning Letters by making the necessary corrections. If, however, a firm's response is inadequate, if no response is received, or if the response disputes FDA's findings, the appropriate District or Center will initiate follow-up action as appropriate to resolve the dispute and achieve compliance. These follow-up actions may include further communications to clarify the Agency's position, and/or an enforcement action.

The vast majority of Warning Letter disputes are resolved through informal communications between the firm and the District or Center.

It is the policy of FDA to decentralize action-taking and decision-making authority to the organizational component that will provide the most timely, economical, and effective administration of Agency programs. Therefore, Title 21, *Code of Federal Regulations* §10.75 establishes a process in which an interested party may request internal review of FDA decisions through established channels of supervision and review. Through this process, the supervisor of an FDA employee may review a decision or action of the employee, at the request of an interested or aggrieved party, such as a company regulated by FDA. If the party who requested the internal review is still dissatisfied following the first level of supervisory review, the party may request internal review at the next level, and, if necessary, succeeding levels through the established Agency channels of supervision or review.

Review of the matter by a Center Director or the Office of the Commissioner may be requested to resolve an issue that cannot be resolved at lower levels within the Agency. The authority to hear and resolve §10.75 requests to the Commissioner has been delegated to the Office of the Ombudsman in the Office of the Commissioner. Delegations of authority are important to the operation of the Agency. Without them, the Agency could not function efficiently, since nearly all authority to carry out FDA's regulatory functions resides with the Commissioner. The Agency's delegations of authority allow the Commissioner and other officials to convey their authorities to subordinate officials so they may carry out the Agency's activities and functions. See *FDA Staff Manual Guide, Volume II - Delegations of Authority*, September 20, 2007, available at: http://www.fda.gov/smg/vol2/1410/1410.html.

Although FDA regulations do not impose any specific time frame for responding to §10.75 requests, the Agency attempts to respond to these requests in a reasonable and timely manner. In responding to such requests, the Agency gives priority to matters that involve significant policy questions or unusual situations that have a particularly significant or immediate public health impact, and, therefore, require immediate review.

Between 2002 and 2006, the Center for Devices and Radiological Health (CDRH) received 105 §10.75 requests related to Agency actions or decisions during pre-market review. The average time each year to make a decision about these requests within CDRH ranged from eight months for those received in 2003 to three months for those received in 2006.

During the same time period, the Office of the Ombudsman in the Office of the Commissioner received a total of six §10.75 requests. These requests involved decisions made in various components of the Agency, such as Centers and offices within the Office of the Commissioner. To date, we are aware of only one instance in which a §10.75 appeal was requested for a Warning Letter. The time it took for the Office of the Commissioner to make a decision about these appeals was: 16 months (for the one received in 2002), 27 months (for one received in 2003), 4 months (for the second one received in 2003), 8 months (for the one received in 2004), 8 months (for the one received in 2005), and 23 months (for the second one received in 2005). No appeals were received in 2006.

As explained in the Agency's July 26, 2007, letter, FDA's regulation provides that appeals under §10.75 do not stay an enforcement action. Were it otherwise, firms could use the §10.75 process to shield themselves from enforcement actions or potential adverse judgments. The Agency, however, believes that the §10.75 appeal process is a valuable and effective mechanism for resolving disputes concerning Agency actions, and wishes to assure you that it strives to handle all dispute resolution matters with objectivity and impartiality. Your letter specifically references a Warning Letter appeal and related civil money penalty case involving a medical device firm charged with violating FDA's Medical Device Reporting (MDR) requirements, and suggests that FDA used the firm's §10.75 request "to string [the firm] along while FDA [was] actually preparing an enforcement action." Although we believe it is not appropriate to discuss this matter because it is still being litigated by the company, we do wish to respond to your concerns.

In the civil money penalty case mentioned in your letter, the firm received a Warning Letter in February 2004, detailing violations resulting from the firm's failure to file MDRs for serious injuries associated with its devices within 30 days of becoming aware of them. Prior to the February 2004 Warning Letter, the firm had received a Warning Letter and three untitled letters detailing similar violations. These letters were in addition to Lists of Inspectional Observations, FDA Form- 483s, bringing the same violations to the attention of the firm's management. The firm responded to the 2004 Warning Letter by requesting a regulatory meeting with the District office. In March 2004, the District Compliance Director and other management personnel met with the firm to discuss the Warning Letter and further explain FDA's position. On March 22, 2004, the firm wrote a follow-up letter to the District office challenging FDA's interpretation and application of the MDR regulation. The firm wrote a second letter on April 2, 2004, further stating its disagreement with FDA's interpretation of the regulation. On April 15, 2004, the District office responded to the letters, reiterating its position that the company had violated the MDR requirements. Between April 13 and September 27, 2004, FDA exchanged 13 letters with the firm. The firm's objections to the Warning Letter were elevated through the appropriate channels of regulatory review. The matter was elevated from the District to the appropriate compliance and management personnel in CDRH, until it reached the Center Director. On November 10, 2004, after reviewing the matter, the Center Director issued a letter to the firm upholding the Warning Letter, stating that CDRH would be willing to process the events as MDRs without further dispute if the firm wished to submit the MDRs to FDA. The letter stated that the Center's decision was final, and noted that further communications from the firm regarding this matter would be treated as an appeal under §10.75, and forwarded to the Commissioner. On November 16, 2004, the firm requested that CDRH forward the matter to the Commissioner for review.

Although the eight-month delay in responding to the firm's §10.75 request was regrettable, we do not believe that the firm was prejudiced by this event—nor did the Agency in any way benefit by the delayed response. The Agency made many reasonable attempts to resolve this dispute at the District and Center levels. There were appropriate levels of management oversight and review at every phase of the dispute. Even after the enforcement action was filed, CDRH made several good faith attempts to reach a reasonable settlement.

Moreover, despite the fact that the parties were unable to reach a settlement, the firm had the opportunity to have its arguments and defenses fully heard and adjudicated in a neutral and unbiased administrative proceeding, and has continued to operate its business without interruption.

While it is true the Commissioner's office consulted with FDA's Office of Chief Counsel regarding the dispute, these contacts were not improper, and did not hinder the fair and impartial decision-making concerning the firm's §10.75 request. The ultimate decision to deny the request was made by the Office of the Commissioner.

Thank you for your continued interest in this matter. Please let us know if we can be of further assistance. A similar letter has been sent to former Ranking Member Whitfield.

Sincerely,

Stephen R. Mason
Acting Assistant Commissioner
for Legislation

cc: The Honorable John D. Dingell, Chairman
Committee on Energy and Commerce
The Honorable Bart T. Stupak, Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce